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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/680,358

Applicant(s)

SCHWAB ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-27,29-40 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-27,29-40 and 49-51 is/are rejected.
- 7) ☒ Claim(s) 15 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This action is in response to applicant's amendment received on 10/18/2007.

#### ***Allowable Subject Matter***

2. The indicated allowability of claims 10, 11, 15, 16, 27, 30, 32-36, 50, and 52 is withdrawn in view of the newly discovered reference(s) to Fakhrai, Burgin, and Zinkel. Rejections based on the newly cited reference(s) follow.

#### ***Claim Objections***

3. Claims 1, 21, and 40 are objected to because of the following informalities: claims 1, 21, and 40 state, ... wherein with the guide surfaces of the first and second guide members oriented towards one another, the guide flanges are on opposite sides of the first and second guide members. The examiner does not believe that the guide flanges are on opposite sides of the guide members. The examiner believes that the guide flanges are on the same side of each guide member and create a substantially L-shaped guide member, wherein when the guide surfaces are facing one another the guide flanges are opposite each other along the length of the guide members. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 9, 12-14, 17-21, 26, 29, and 37-40 are rejected as understood under 35 U.S.C. 102(b) as being anticipated by Weissman (U.S. Patent 4,758,159).

Regarding claim 1, Weissman discloses a device comprising a proximal portion including a frame and a distal portion including first and second guide members extending distally from the frame (see Figure 1 below). The first and second guide member include opposite first and second sides extending between a proximal end and a distal end, a guide surface extending from the proximal end to the distal end between the first and second sides, and a guide flange extending along only one of the first and second sides projecting from a guide surface of the corresponding one of the first and second guide members toward the guide surface of the other of the first and second guide members, wherein the guide surfaces of the first and second guide members oriented towards each other, a first guide flange is aligned with a side of the first guide member and a second guide flange is aligned with a side of the second guide member, wherein the first and second guide flanges are on opposite sides of the first and second guide members. The examiner believes that when the device of Weissman is viewed from the distal end the guide members form L-shapes. The examiner believes that the guide flange of one guide member is on the right side of the guide member and the guide flange of the other guide member is on the left side of the guide member.

Regarding claim 9, Weissman discloses a device wherein guide surfaces are planar.

Regarding claim 12, Weissman discloses a device wherein the frame includes a stationary arm and a moveable arm, wherein one of the first and second guide members is coupled to the stationary arm and the other of the first and second guide

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members is coupled to the moveable arm. Regarding claim 13, Weissman discloses a device wherein the stationary arm and the moveable arm are transversely oriented to the first and second guide members. The examiner believes that the first and second guide members are transversely oriented to the surfaces of the stationary arm and the moveable arm from which the first and second guide members extend. Since the first and second guide members are transversely oriented to the surfaces of the stationary arm and the moveable arm the examiner believes that the first and second guide members meet the limitation of being transversely oriented with the stationary arm and the moveable arm. Regarding claim 14, Weissman discloses an element extending from the stationary arm that is capable of being used as a handle. Regarding claim 17, Weissman discloses a device wherein the guide surfaces are parallel with one another. Regarding claim 18, Weissman discloses a device wherein the frame portion is capable of moving the guide members away from and toward one another while keeping the guide surfaces parallel. Regarding claims 19 and 20, Weissman discloses a device comprising a proximal portion including a frame and a distal portion including first and second guide members extending distally from the arms of the frame. The frame includes a stationary arm and a moveable arm coupled to the stationary arm, wherein the stationary arm and the moveable arm are transversely oriented to the first and second guide members as discussed above. The first and second guide members include a proximal end, a distal end, a first side, a second side, and a guide surface extending from the proximal end to the distal end between the first and second sides, wherein the guide surface of the first and second guide members are oriented towards

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one another. The first and second guide members are capable of moving toward and away from one another by moving the moveable arm relative to the stationary arm.

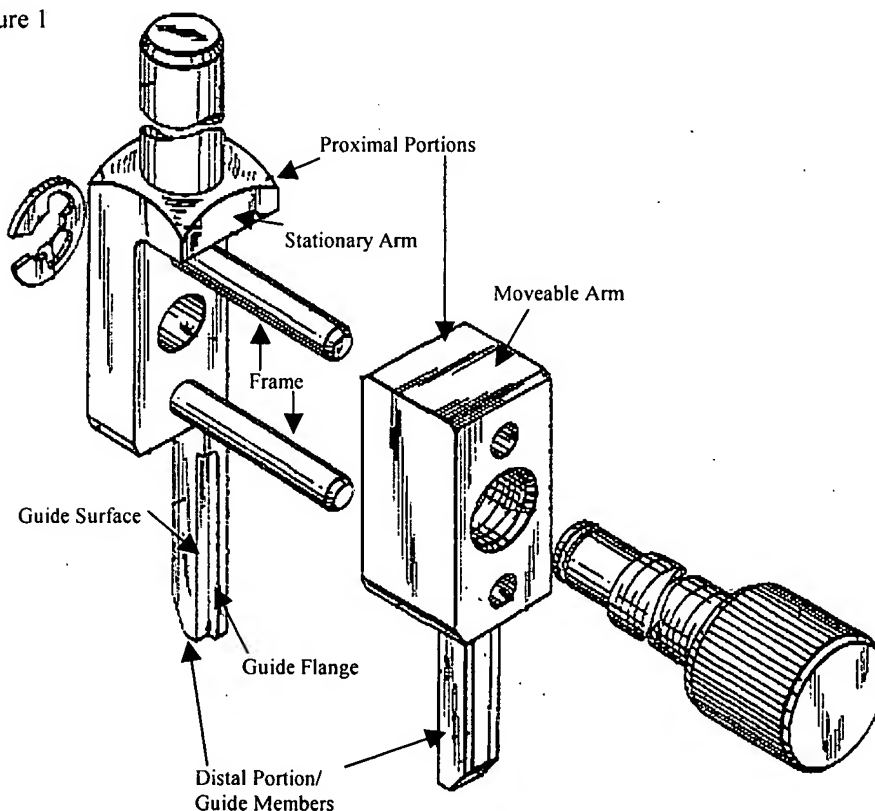
Further regarding claim 20, Weissman discloses a device wherein the guide flange extends along only one of the first and second sides, the guide flange projecting from the guide surface of the corresponding guide member towards the guide surface of the other guide member. Regarding claim 21, Weissman discloses a device wherein a first guide flange is aligned with a side of the first guide member and a second guide flange is aligned with a side of the second guide member, wherein the first and second guide flanges are on opposite sides of the first and second guide members as discussed above. Regarding claim 26, Weissman discloses a device wherein the guide surfaces are planar. Regarding claim 29, Weissman discloses an element extending from the stationary arm that is capable of being used as a handle. Regarding claim 37, Weissman discloses a device wherein the guide surfaces are parallel with one another and the frame portion is capable of moving the guide members away from and toward one another while keeping the guide surfaces parallel. Regarding claim 38, Weissman discloses a device comprising a proximal portion including a frame and a distal portion including first guide member and a second guide member extending along the first guide member. The frame is coupled to the first and second guide members capable of moving the first and second guide members away from one another with the guide surfaces remaining generally parallel, wherein the frame is transversely oriented to the guide members adjacent the proximal ends of the guide members and the guide members define a proximal opening in between capable of receiving an implant for

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positioning between the guide surfaces of the guide members. The first and second guide members include a guide surface oriented toward the guide surface of the other guide member, wherein the guide surfaces are generally parallel with one another.

Regarding claim 39, Weissman discloses a device wherein the frame includes a stationary arm coupled to one of the first and second guide members and a moveable arm coupled to the other of the first and second guide members, wherein the moveable arm is capable of being movably coupled to the stationary arm. Regarding claim 40, Weissman discloses a device wherein the guide members include guide flanges extending along the guide members capable of confining an implant between the guide flanges as the implant is moved along the guide surfaces.

Figure 1



***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-8 and 22-25 are rejected as understood under 35 U.S.C. 103(a) as being unpatentable over Weissman (U.S. Patent 4,758,159) in view of Moskovich (U.S. Patent 5,431,658).

Regarding claims 3-8 and 22-25, Weissman discloses the invention as claimed except for the guide members including an abutment member adjacent the distal end, a support member extending distally from the abutment member, and the guide surfaces including a plurality guide rails. Moskovich teaches a device comprising an abutment member adjacent the distal end of the guide members, a support member extending distally from the abutment member, and the guide surfaces including a plurality of guide rails in order to limit the insertion of the guide members into the patient, to distract two sections of bone, and to prevent the implant from rotating or slipping. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Weissman wherein the guide members include an abutment member adjacent the distal end, a support member extending distally from the abutment member, and the guide surfaces including a plurality of guide rails in view of



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Moskovich in order to limit the insertion of the guide members into the patient, to distract two sections of bone, and to prevent the implant from rotating or slipping.

Regarding claims 6 and 25, the combination of Weissman and Moskovich disclose a device wherein the guide rails terminate at a location along the guide surface adjacent the abutment member.

8. Claims 1, 11-14, 16-21, 29, 30, 32-40, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fakhrai (U.S. Patent 5,088,472) in view of Burgin (U.S. Patent 4,165,746).

Regarding claim 1, Fakhrai discloses a device comprising a proximal portion including a frame (22) and a distal portion including first and second guide (24 and 26) members extending distally from the frame. Each guide member includes opposite first and second sides extending between a proximal end and a distal end, a guide surface extending from the proximal end to the distal end between the first and second side surfaces, and a guide flange extending along only one of the first and second sides and projecting from the guide surface of the guide member. Fakhrai fails to disclose the device wherein the guide surfaces of each guide member face towards one another and the frame comprising a stationary arm and a moving arm. Burgin teaches a device comprising a proximal end including a frame comprising a stationary arm (36) and a moving arm (34) and a distal portion including first and second guide members (54 and 56), wherein the guide surfaces of the guide members are capable of being oriented towards each other in order to produce a clamping force between the guide members (column 3 lines 25-33). It would have been obvious to one having ordinary skill in the art.

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at the time the invention was made to manufacture the device of Fakhrai wherein the guide surfaces of the guide members are oriented towards one another in view of Burgin in order to produce a clamping force between the guide members.

Fakhrai discloses a device comprising a frame in order to move the guide members parallel to each other. Burgin teaches a device comprising a frame including a stationary arm and a moving arm in order to move the guide members parallel to each other. Because both Fakhrai and Burgin teaches device comprising frames, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute on frame for the other in order to achieve the predictable results of moving the guide members parallel to each other.

Regarding claim 11, the combination of Fakhrai and Burgin disclose the device as discussed above wherein the guide surfaces of the first and second guide members have a width between the first and second sides, wherein the width is greater than the width of an implant to be positioned along the guide surface. Regarding claim 12, the combination of Fakhrai and Burgin disclose a device wherein the frame includes a stationary arm and a moving arm, wherein one of the first and second guide members is coupled to the stationary arm and the other of the guide members is coupled to the moving arm. Regarding claim 13, the combination of Fakhrai and Burgin disclose a device wherein the stationary arm and the moving arm are transversely oriented to the first and second guide members. Regarding claim 14, the combination of Fakhrai and Burgin disclose a device wherein the frame includes a handle (Burgin element 30) extending from the stationary arm. Regarding claim 16, the combination of Fakhrai and

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Burgin disclose a device wherein the stationary arm and the moving arm define a C-shaped central opening between (Burgin Figure 4). Regarding claim 17, the combination of Fakhrai and Burgin disclose a device wherein the guide surfaces are parallel with one another. Regarding claim 18, the combination of Fakhrai and Burgin disclose a device wherein the frame has a structure capable of moving the guide members away from and toward one another with the guide surfaces remaining parallel to one another. Regarding claims 19-21, 29, 30, and 32, the combination of Fakhrai and Burgin disclose the limitations of claims 19-21, 29, 30, and 32 as discussed above. Regarding claim 33, the combination of Fakhrai and Burgin disclose a device wherein the stationary arm includes a first vertical extension portion (39) coupled to the first guide member, a lateral extension portion extending from and transversely oriented to the first vertical extension portion, and a second vertical extension (37) opposite the first vertical extension portion. Regarding claim 34, the combination of Fakhrai and Burgin disclose a device wherein the moving arm is coupled with the second vertical extension portion. Regarding claim 35, the combination of Fakhrai and Burgin disclose a device wherein the moving arm includes a lateral extension portion extending transversely to the second vertical extension portion of the stationary arm. Regarding claim 36, the combination of Fakhrai and Burgin disclose a device wherein the moving arm includes a vertical extension portion (35) opposite the second vertical extension portion of the stationary arm, wherein the vertical extension portion of the moving arm is aligned with the first vertical extension of the stationary arm. Regarding claims 37-40, the combination of Fakhrai and Burgin disclose the limitations of claims 37-40 as discussed

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above. Regarding claims 49-51, the combination of Fakhrai and Burgin disclose the limitations of claims 49-51 as discussed above.

9. Claims 3-9 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fakhrai (U.S. Patent 5,088,472) in view of Burgin (U.S. Patent 4,165,746) further in view of Moskovich (U.S. Patent 5,431,658).

Regarding claims 5 and 24, the combination of Fakhrai and Burgin disclose a device wherein the guide surfaces include guide rails (Fakhrai Figure 2). The combination of Fakhrai and Burgin fail to disclose the device further comprising an abutment member adjacent the distal end of the guide members opposite the guide surface and a support member extending distally from the abutment member. Moskovich teaches a device comprising guide member further comprising an abutment member adjacent the distal end of the guide members opposite the guide surface and a support member extending distally from the abutment member in order to limit the insertion of the guide members and to distract two adjacent portions of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Fakhrai and Burgin wherein the guide members further include an abutment member and a support member in view of Moskovich in order to limit the insertion of the guide members and to distract to adjacent portions of tissue.

Regarding claims 6 and 25, the combination of Fakhrai, Burgin, and Moskovich disclose a device wherein the guide rails terminate along the guide surface adjacent the abutment member. Regarding claim 7, the combination of Fakhrai, Burgin, and

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Moskovich disclose a device wherein the guide surface extends distally from the guide rails along the support member. Regarding claims 8, 9, and 26, the combination of Fakhrai, Burgin, and Moskovich disclose a device wherein the guide surface is planar along the guide member and the support member.

10. Claims 10 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fakhrai (U.S. Patent 5,088,472) in view of Burgin (U.S. Patent 4,165,746) further in view of Moskovich (U.S. Patent 5,431,658) further in view of Zinkel (U.S. Publication 2004/0024291)

Regarding claims 10 and 27, the combination of Fakhrai, Burgin, and Moskovich disclose the invention as claimed except for the proximal end of the guide member including a dovetail configuration and the frame comprising a corresponding receptacle. Zinkel teaches a device wherein the proximal end of a guide member includes a dovetail configuration and a frame includes a corresponding receptacle in order to connect the guide member to the frame. Because both the combination of Fakhrai, Burgin, and Moskovich and Zinkel teach devices comprising connections between the guide members and the frame, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one connection for another in order to connect the guide members to the frame.

***Allowable Subject Matter***

11. Claims 15 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

12. Applicant's arguments with respect to claims 1, 3-27, 29-40, and 49-51 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds for rejection and withdrawn previously indicated allowability as discussed above making this office action non-final.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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